

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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|--------------------------------|---|-----------------|
| SHIRE ORPHAN THERAPIES LLC and |) | Civil Action |
| SANOFI-AVENTIS DEUTSCHLAND |) | |
| GMBH, |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | |
| |) | |
| FRESENIUS KABI USA, LLC, |) | |
| |) | |
| Defendant. |) | No. 15-1102-GMS |

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Wilmington, Delaware
 Friday, December 15, 2017
 10:00 a.m.
 Telephone Conference

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BEFORE: HONORABLE GREGORY M. SLEET, Senior Judge, U.S.D.C.,
 District of Delaware

APPEARANCES:

DEREK J. FAHNESTOCK, ESQ.
 Morris, Nichols, Arsht & Tunnell LLP
 -and-
 EDGAR J. HAUG, ESQ.,
 SANDRA KUZMICH, Ph.D., ESQ.,
 LAURA A. CHUBB, ESQ., and
 ELIZABETH MURPHY, ESQ.
 Haug Partners LLP
 (New York, NY)
 Counsel for Plaintiffs

KAREN E. KELLER, ESQ.
 Shaw Keller LLP
 -and-
 WILLIAM G. JAMES, ESQ., and
 JOHN COY STULL, ESQ.
 Goodwin Procter LLP
 (Washington, DC)

Counsel for Defendant

1 THE COURT: Good morning, counsel. Who is on
2 the line for the plaintiffs, please.

3 MR. FAHNESTOCK: Good morning, Your Honor. This
4 is Derek Fahnestock from Morris Nichols for plaintiffs.
5 With me on the line from Haug Partners are Ed Haug, Sandra
6 Kuzmich, Laura Chubb, and Elizabeth Murphy.

7 THE COURT: Good morning, everyone.
8 Who is going to discuss the defendant's motion
9 with me for the plaintiffs?

10 MS. KELLER: Good morning, Your Honor. Karen
11 Keller --

12 THE COURT: For the plaintiffs, who is going to
13 be arguing?

14 MR. FAHNESTOCK: That would be Ed Haug, Your
15 Honor.

16 THE COURT: Thanks. Let's hear intros for the
17 defendant, please.

18 MS. KELLER: Good morning, Your Honor. Karen
19 Keller from Shaw Keller on behalf of Fresenius Kabi. With
20 me today is Bill James and John Coy Stull from Goodwin
21 Procter.

22 THE COURT: Good morning.
23 Who is going to argue the motion for you,
24 counsel?

25 MR. JAMES: That would be Bill James, Your

1 Honor.

2 THE COURT: Okay.

3 Have I accounted for everyone in the case?

4 Okay.

5 Let's go, Mr. James.

6 MR. JAMES: Thank you, Your Honor. We
7 appreciate you hearing us on this issue.

8 Your Honor, we submitted this motion to amend in
9 March of this year, and a lot has happened in the case since
10 then.

11 Just as a preliminary matter, Your Honor should
12 know that the experts on both sides have addressed this
13 issue. Expert depositions have occurred on this issue. The
14 parties have written this issue up in their submissions in
15 the pretrial order, which is due on Monday. From our point
16 of view, Your Honor, this issue is trial-ready, and it will
17 not affect the timing of the trial or the schedule in any
18 regard.

19 THE COURT: Let's stop right there, because
20 those are important developments. We may have a rather
21 brief conversation this morning.

22 Mr. Haug, would you comment about what you have
23 just heard, please, how you think it should impact the
24 Court's ruling.

25 MR. HAUG: Yes, Your Honor, be glad to.

1 I don't entirely agree with what Mr. James just
2 said. The motion to amend was, as Your Honor knows from the
3 papers, filed seven months after the deadline, and it was
4 about a month or so before the end of fact discovery. And
5 long --

6 THE COURT: Mr. Haug, I know you have got your
7 talking points this morning. You are going to have to
8 answer my question. That was to address directly the
9 developments that Mr. James has just reported to the Court
10 and how you think they might impact. I have read your
11 papers, so I know what you want to argue. Please give me
12 that much. Answer my question. All right?

13 MR. HAUG: I am sorry, Your Honor.

14 We did take fact discovery to the extent we
15 could on this issue. There were two, I think, two people
16 that were deposed on it. And there were also expert reports
17 that addressed the issue. So Mr. James is correct on that.
18 It is addressed in the pretrial order to that extent.

19 THE COURT: Do you disagree when he says the
20 case is trial-ready?

21 MR. HAUG: Well, I don't know if this issue is
22 in the case. If this issue comes into the case with Your
23 Honor's ruling now, then I think the case is not
24 trial-ready. I think there would be additional discovery
25 that we would want to take to avoid prejudice.

1 THE COURT: Tell me what additional discovery.

2 I know you have made assertions of prejudice. I rather
3 agree with the defendants in the reply brief that the
4 assertions are rather vague and quite frankly not well taken
5 by me. I want you to tell me how you would be prejudiced if
6 I grant this motion today and order this case to trial at
7 the appointed time.

8 MR. HAUG: The prejudice, Your Honor, I think
9 would be, we did not have the opportunity to go to Germany,
10 which is where all the documents are, going back 20, 25
11 years, to search for documents on a patent that is not the
12 patent in suit, and to talk to people, to the extent they
13 are still available, namely, inventors and other people. We
14 didn't have the opportunity to do that because of where we
15 were in the schedule in the case.

16 THE COURT: Mr. James, there is your target.
17 Let me hear from you.

18 MR. JAMES: Thank you, Your Honor.

19 Your Honor, a couple of things. One is that all
20 of the discovery that would -- first of all, I don't think
21 discovery is really relevant to this issue, because this is
22 an obviousness-type double patenting issue. The issue is
23 really just comparing the claim of the referenced patent
24 that we have found and asserted to the claim of the, the
25 asserted claim of the '333 patent and deciding whether that

1 is an obvious variant or not.

2 Discovery of what happened inside of Hoechst 30
3 years ago isn't relevant to that issue as an initial matter.

4 Second is that we took discovery, we asked for
5 discovery of Hoechst in this case on Bradykinin antagonists.
6 We actually, as we set out in our papers, we propounded a
7 document request that specifically called for patents owned
8 by the plaintiffs that relate to Bradykinin antagonists.
9 The plaintiffs told us they were going to produce the
10 patents --

11 THE COURT: When did you make that request?

12 MR. JAMES: We made that request in 2016, well
13 in advance of the date in Your Honor's scheduling order to
14 amend the pleadings. If we had gotten that discovery, we
15 wouldn't be here today.

16 We did take discovery of the European inventors,
17 to the extent that they were provided to us. We got
18 documents produced to us from Hoechst in Germany. I think
19 they had every opportunity to search for these documents.
20 They are actually called for by our discovery requests.

21 I don't think there is any additional discovery
22 that would be necessary here.

23 As we said in our papers, we weren't seeking
24 additional discovery from them. We never did. We think we
25 have everything we need to go at trial.

1 THE COURT: Mr. Haug.

2 MR. HAUG: There were never any specific
3 discovery requests for the '803 patent, which is what we are
4 talking about here. No one knew that was an issue in the
5 case. We certainly didn't. It wasn't raised by the
6 defendants at any point until well after the cutoff to amend
7 the pleadings and add this other new defense. It's not like
8 we were asked for an actual document or patent and didn't
9 give it to them. That is not the case at all.

10 In addition, this is a public document. This is
11 an issued patent that they have had available to them for
12 many, many years, probably. I don't think there is -- there
13 was nothing we could have produced earlier based on what was
14 going on in the case. We simply didn't know about this new
15 defense until seven months after the cutoff for amending the
16 pleadings. And they have shown, we believe, no good cause
17 for the delay.

18 We did the best we could, Your Honor, to take
19 the fact discovery and expert discovery at the very end of
20 the discovery period because we had not had a ruling on this
21 motion, so we did the best we could to address it.

22 But in answer to your question about prejudice,
23 were we able to do everything we would have done, had the
24 defense been properly added to the case, according to the
25 scheduling order in the case, no, we didn't have the

1 opportunity to do that in my judgment.

2 THE COURT: It's been my experience, with all
3 due respect, Mr. Haug, everything that could be done doesn't
4 necessarily need to be done, particularly in patent cases.

5 MR. HAUG: I agree, Your Honor.

6 Mr. James, your last word on this.

7 MR. JAMES: Your Honor, the point that Mr. Haug
8 is making that nobody knew about this patent is exactly the
9 reason that we didn't find it initially, because it's not
10 prior art. It's a later-filed patent application that
11 expires earlier. It isn't referenced on the face of the
12 patent in suit, so you couldn't find it, it's not referenced
13 in the patent family, which most obviousness type
14 double-patenting references are.

15 In fact, it was never even disclosed to the
16 Patent Office, which it should have been, as we pointed out
17 in our reply brief on Page 2. This patent was essentially
18 hidden and unknown to anyone until we sort of discovered it
19 by happenstance just before we brought it to Your Honor's
20 attention last March.

21 THE COURT: Okay. My ruling is essentially, Mr.
22 Haug, get ready for trial. I am going to permit the
23 amendment. I believe that the defendant has been diligent
24 in its efforts under the circumstances, given the unusual
25 nature of the '803.

1 And also, I am not quite sure why plaintiff
2 didn't produce the '803 when asked to. I am not inviting a
3 comment. That's based on my reading of the papers. I
4 think, to the extent that you feel that you have been
5 aggrieved by the Court's ruling, you will have recourse
6 posttrial, if not even pretrial, if you desire to take that
7 route.

8 Anything else, counsel?

9 MR. JAMES: Nothing from me, Your Honor.

10 MR. HAUG: No, Your Honor. Thank you.

11 (Matter concluded at 10:13 a.m.)

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13 Reporter: Kevin Maurer